Richard_Denison@environmentaldefense.org on 10/06/2003 01:42:17 PM

To: oppt.ncic@epamail.epa.gov, ChemRTK HPV@EPA, chem.rtk@epamail.epa.gov, Karen Boswell/DC/USEPA/US@EPA, jheinze@johnadams.com
cc: LUCIERG@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the Linear Alkylbenzene (LAB) Sulfonic Acids Category

(Submitted via Internet 10/6/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and jheinze@johnadams.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Linear Alkylbenzene Sulfonic Acids Category.

The test plan and robust summaries for the linear alkylbenzene (LAB) sulfonic acids category was submitted by the LAB Sulfonic Acids Coalition, which is comprised of 5 companies. Three CAS numbers are included in this submission: benzene sulfonic acid, C10-16 alkyl derivatives (CAS# 68584-22-5), benzene sulfonic acid, dodecyl (CAS# 27176-87-0) and benzene sulfonic acid, tridecyl (CAS# 25496-01-9). In addition, the sponsor proposes to use a considerable amount of surrogate data from the linear alkylbenzene sulfonates (LAS) to fulfill HPV-SIDS endpoints, particularly in the area of mammalian toxicity.

In general, we agree with the proposed category and the use of surrogate data. These substances represent numerous chemicals based on alkyl chain length and all the substances are similar in structure, physiochemical properties and patterns of toxicity, all of them being relatively non-toxic chemicals. However, we have several questions regarding the plan with respect to how it relates to a previously submitted test plan for the linear and branched alkylbenzene sulfonic acids and derivatives, and we also question the adequacy of some of the existing data due to a lack of studies meeting GLP. Therefore, based on the current information provided in the test plan and robust summaries, we disagree that no new studies are needed. If additional information is provided , we would be glad to reevaluate the test plan to determine if it meets HPV requirements.

The LAB sulfonic acids are apparently used as intermediates in the manufacture of LAS surfactants, a major cleaning agent for laundry detergents and other cleaning products. The sponsor states that industrial hygiene practices are effective in minimizing worker exposure. However, a TLV has not been established and no information is provided on the magnitude of worker exposure. Likewise, the sponsor states that environmental releases and consumer exposure for LAB sulfonic acids are minimal, but no quantitative information is provided to substantiate this claim. Inasmuch as the LAS surfactants are used in a wide array of consumer products and are used as surrogates for the LAB sulfonic acids, environmental releases and worker and consumer exposure information on the LAS surfactants should be provided, since the sponsor has, in essence, included them in the LAB sulfonic acids category.

The sponsor previously submitted a test plan for the linear and branched

alkylbenzene sulfonic acids and derivatives. This test plan encompassed different CAS numbers than that for the LAB sulfonic acids, even though the two sets of substances possess very similar structures and other properties. However, the connection between the two test plans is not discussed. This raises several questions, which are posed below (1a-c), followed by our additional specific comments (2-4):

1a. Is the current test plan also intended as a response to our comments on the previous plan? We were concerned with an excessive reliance on data to be generated under the ICCA initiative that are not publicly available.

1b. Why not combine, at least in part, the two test plans?

1c. How are the two test plans related to the Linear alkylbenzene sulfonates category to be reviewed at the November OECD SIAM17 meeting?

2. The sponsor states that there are 15 repeat dose studies on the LAS surfactants and that one was selected for inclusion in the robust summaries. It would be helpful if the other studies were summarized and referenced in the robust summaries. Also, the methods for the histological analyses of the one repeat dose study cited are not presented and this study was not conducted under GLP. For these reasons an additional repeat dose study may be needed on at least one of the three members of the proposed category.

3. The reproductive and developmental toxicity studies conducted on the LAS surfactant surrogate were not conducted under GLP, although they do seem to be reasonable studies. Nevertheless, the sponsor may want to consider a combined repeat dose, developmental and reproductive study.

4. The in vivo genetic toxicity study used CAS# 85536-14-7 as the test substance. What is this material and how is its use justified in fulfillment of the HPV SIDS requirements for this category?

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense